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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,765	07/17/2003	Arthur Castle	044921-5124	9148

9629 7590 11/29/2005

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
WONG, JENNIFER SHIN SHIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,765	CASTLE ET AL.	
	Examiner	Art Unit	
	Jennifer Wong	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10 and 46-55, drawn to methods to identify invariant gene expression, classified in class 435, subclass 6.

   II. Claims 11-17 and 28-34, drawn to probes and arrays containing said probes, classified in class 536, subclass 24.3.

   III. Claims 18-27, 35-45, and 56, drawn to methods to normalize gene expression assay data, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of invention II are not required to practice the method steps of invention I.

Inventions I and III are drawn to patentably distinct methods requiring the use of different reagents, involving different process steps and having different outcomes or objectives. In particular, the method of invention I requires the use of a gene expression database and involves querying and the statistical analysis of said database in order to accomplish the objective of identifying a gene that is consistently expressed across different cell or tissue types of an organism. Invention III requires nucleic acids and

arrays and involves performing hybridization and assays to detect said hybridization, and calculating the dividend of the expression levels of a gene and a control gene, with the objective to of normalizing gene expression data. The methods of inventions I and III are novel and unobvious over one another.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of invention II are not required to practice the method steps of invention III.

3. Further, should Applicants elect invention I or III, this group are subject to an additional restriction requirement as follows:

The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Invention I and III read on patentably distinct inventions drawn to multiple cell or tissue types. The inventions claim distinct sets of a number of control probes set selected from at 10, 25, 50 cell or tissue types.

The cell or tissue types comprise sets of 10, 25, or 50 cell or tissue types. Each of these cells and tissue types consists of specific molecular, structural, and physiological properties that characterize biological systems that have distinct functions that maintain organisms. Given the differences in structure and function, the Markush group set forth in inventions I and III is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement.

A patent and non-patent literature search of the number of cell or tissue types expressed in an organism is not coextensive with one another. For example, an epithelial cell that is expressed in rat is chemically, structurally and functionally distinct than cardiac, neural, digestive, intestinal, optic, bronchial, lymphatic, muscular, and skeletal tissues expressed in said rat. Further, a reference which renders obvious or non-novel an epithelial cell that is expressed in rat would not also necessarily render obvious or non-novel cardiac, neural, digestive, intestinal, optic, bronchial, lymphatic, muscular, and skeletal tissues expressed in said rat. Similarly, a finding that the an epithelial cell that is expressed in rat is novel and unobvious over the prior art would not necessarily extend to a finding that cardiac, neural, digestive, intestinal, optic, bronchial, lymphatic, muscular, and skeletal tissues expressed in said rat is also novel and unobvious over the prior art. Accordingly, a search of the total number of cell or tissue types in claims 4-6 and 49-51 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed cell or tissue types. Accordingly, Applicants are required to elect one (1) cell or tissue type selected from the group consisting of 10, 25, 50 cell or tissue types to be examined with respect to claims 4-6 and 49-51.

4. Further, should applicants elect inventions I or III, these groups are subject to an additional restriction requirement as follows:

The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Invention I and III

read on patentably distinct inventions drawn to multiple genes. The inventions claim distinct sets of a number of genes set selected from at least 10, 25, 50, or 100 genes.

These numbers of genes comprising nucleic acid sequences of a gene that is expressed in normal and diseased cell or tissue types. Each of these genes are structurally, and chemically distinct from one another. Applicant must elect a set of genes to be examined. Given the differences in structure and function, the Markush group set forth in invention I and III is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement.

A patent search and non-patent literature search of these nucleic acid sequences would not be coextensive with one another. For example, a search for a set of probes of 10 normally expressed genes that is consistently expressed in a rat epithelial cell would not be coextensive with a search of 100 probes of a gene that is normally consistently expressed in rat cardiac tissue. Further, a reference that renders obvious or non-novel set of probes that hybridizes to 10 genes that is normally expressed in a rat epithelial cell would not render obvious or non-obvious 100 probes of a gene that is normally expressed in rat cardiac tissue. Similarly, a finding that the set of probes that hybridizes to 10 normally expressed genes that is consistently expressed in a rat epithelial cell is novel and unobvious would not necessarily extend to the finding that the 100 probes of a gene that is normally expressed in rat cardiac tissue. Accordingly, a search of the total number of genes from the claims 19-22 and 36-39 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences.

Accordingly, Applicants are required to elect set of a number of genes selected a set of 10, 25, 50, or 100 genes. Note that this is not a species selection.

5. Further, should Applicants elect invention II, this group is subject to an additional restriction requirement as follows.

The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Invention II read on patentably distinct inventions drawn to multiple genes. The claims encompass nucleic acids that hybridize or exhibit 95% sequence identity of a gene of Table 1. The 200 genes of Table 1 consist of distinct nucleotide sequences, and a further restriction is applied to each invention. Applicants must elect a single gene or combinations of 10, 25, 50, or 100 probes of Table 1 to be examined.

It is noted that each gene and nucleic acid of said gene constitute distinct chemical compounds and each has a distinct functional property. The chemical structure of each gene and nucleic acid of said gene is distinct from each of the other polymorphisms. Specifically, claims 28-33 claim distinct sets of nucleic acid probes that hybridize to a gene of Table 1 or comprise 95% nucleotide sequence identity to genes of Table 1. Each of these primers consists of a distinct nucleic acid sequence, has a different melting point, and binds to a different nucleic acid sequence, and thereby has a different biological function. Given the differences in structure and function, the Markush group set forth in claims 28-33 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. For example, a M74439mRNA I at gene is chemically, structurally and functionally distinct from a

polynucleotide comprising rc A1073001 at gene. Further, a search for a nucleic acid M74439mRNA I at gene would not be co-extensive with a search for a nucleic acid comprising rc A1073001 at gene. Accordingly, a search of the number of genes from the claims 11-17 and 28-34 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, Applicants are required to elect Applicants must elect a set of probes from the probe sets of claims 11-17 and 28-34. For instance, a set of probes in which 10 probes that hybridizes to 10 genes of Table 1. Note that this is not a species selection.

6. The inventions are distinct for the reasons given above and have required a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, a patent, non-patent, and sequence searches of inventions I-III require different searches that are not co-extensive and distinct from one another. For example, a literature and patent search for the assay methods to identify invariant gene expression is not co-extensive with the nucleotide sequences of probes or the arrays containing said probes (invention II), or the methods to normalize gene expression data (invention III). Similarly, a literature and patent search for the nucleic acids of invention II are not co-extensive and the methods of inventions I and II. Likewise, the non-patent and patent search for the methods to normalize gene expression data of invention III is not co-extensive with the methods of invention I or the nucleic acids of invention II. A finding that the methods to identify invariant gene expression of invention I is anticipated or obvious over the prior art would not extend to

a finding that the probes of inventions II and the methods to normalize gene expression data is also anticipated or obvious over the prior art. Likewise, a finding that the methods to identify invariant gene expression of invention I are novel and unobvious over the prior art would not necessarily extend to the gene sequences the probes of inventions II and the methods to normalize gene expression data are also novel and unobvious over the prior art. Accordingly, the examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Wong whose telephone number is (571) 272-1120. The examiner can normally be reached on Monday-Friday; 8 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER

Jennifer Wong